

Docket No. 371-20-055

PATENT

11046 U.S. PTO
09/833961

04/11/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Helix Medical, Inc.

Filed: herewith

Art Unit: unknown

Serial No. unknown

Examiner: unknown

For: MEDICAL DEVICES HAVING ANTIMICROBIAL PROPERTIES

#2

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.56

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure requested by 37 CFR 1.56, Applicant submits an Information Disclosure Statement and a copy of each referenced cited in Information Disclosure Statement.

Discussion of the references:

U.S. Patent No. 5,314,470, assigned to the assignee of the present application, discloses a soft voice prosthesis which includes a rigid stiffening ring inserted into a groove in the soft body of the prosthesis. Though the ring stiffens the body adjacent the valve it does not prevent distortion of the body by muscular movement or distortion of the valve by growth of yeast.

U.S. Patent No. 5,578,083 issued November 26, 1996, discloses the use of a stiff cartridge to support the soft silicone prosthesis and to provide a seat for the valve. However, microbial growth still proceeded to a point at which the valve could not reliably seal.

Microbial growth on the valve can also cause distortion of the shape of the valve or form wrinkles in the body of the valve which prevents the valve from closing. Leaking also appears to be due to distortion of the valve body adjacent to the seat of the valve and to microbial growth on the seat. Forming the valve with an arcuate dome shape increased resistance to folding or bending of the valve. However, some valves still leaked after extended placement in a fistula.

In U.S. Patent No. 3,932,629, Margraf discloses the use of a silver-heparin-allantoin complex to form non-thrombogenic, self sterilizing surface on prosthetic valves or arterial grafts. The

complex can be coated or impregnated into the surface of the valve or graft.

In U.S. Patent No. 4,054,139, Crossley coats the surface of a urinary tract catheter with Ag or Ag compounds by dispersing silver or its compound in resin. The surface is abraded to expose the silver material. The coating contains 10% by weight of silver (col 4, line 10). The coating can be extremely thin such as those deposited by electroless deposition (col 4, lines 16-18).

In U.S. Patent No. 4,563,485, Fox, Jr. et al discloses use of silver norfloxacin or silver perfloxacin to render muscular graft prosthesis formed from resins such as silicone infection resistant.

Fox Jr. et al., utilizes silver metal salts of sulfonamides or other antimicrobials for the same purpose.

Fox Jr. et al., discloses and claims a method of preparing an infection resistant material by solvent impregnation of the material with a silver salt and another compound and reaction in situ to form a silver salt.

In U.S. Patent No. 4,615,705, Scales et al., provides a bioerodible silver coating on the surface of endoprosthetic orthopaedic implants to render the surface antimicrobial.

Fox Jr. et al., discloses the use of a complex of a silver salt and chlorhexidine to add antimicrobial properties to biomedical polymers such as silicones.

In U.S. Patent No. 4,603,152, Laurin, et al. discloses mixing an oligodynamic material such as a salt of silver, gold, platinum, copper or zinc with a resin to form an antimicrobial coating for catheters.


In U.S. Patent No. 4,483,688, Akijama coats an oligodynamically active silver, gold or copper salt on the periphery of a tubular catheter.

Modak et al. and Darouiche et al. discloses the use of triclosan to silicone medical devices such as catheters to inhibit microbial growth. By coating the agent onto the surface of the device or soaking the device in swelling agent and then in a solution containing triclosan to introduce triclosan into the device.

When soft prostheses were compounded with antimicrobial agents such as silver compounds at a level which resists growth of microorganisms, it was discovered that the prosthesis was irritating to and/or toxic to tissue in contact with the prosthesis.

The Commissioner is hereby authorized to charge payment of any patent assignment recording fees under 37 CFR 1.17 or credit over-payment to Deposit Account No. 10-0192. A duplicate copy of this sheet is attached.

Respectfully submitted,


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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

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